

JUL 2 1999

Ms. Kathleen Sanzo  
Morgan, Lewis & Bockius LLP  
1800 M Street, NW  
Washington, DC 20036-5869

Dear Ms. Sanzo:

This is in regard to your submission of October 7, 1997, on behalf of your client BASF AG, concerning the genetically modified Phytaseed® producing canola lines: MPS961, MPS962, MPS963, MPS964, and MPS965. According to the submission, the new canola varieties produce a 3-phytase enzyme derived from *Aspergillus niger*. This enzyme can be utilized in animal feed to increase the digestibility of plant phytate.

As part of bringing the consultation with FDA regarding this product to closure, you submitted a summary of a safety and compositional assessment concerning the new canola lines on November 13, 1997. This communication informed FDA of the steps taken by BASF AG to ensure that the products comply with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and compositional assessments BASF AG has conducted, it is our understanding that BASF AG has concluded that canola grain (seed) derived from the new varieties is not materially different, except for the intended effect, in composition, safety, and other relevant parameters from canola grain (seed) currently on the market, and that the genetically modified canola does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0052. This file will be maintained in the Office of Premarket Approval.

Based on the information you have presented to FDA, we have no further questions concerning canola lines, MPS961, MPS962, MPS963, MPS964, and MPS965 at this time. However, as you are aware, it is your client's responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely,

/s/

Alan M. Rulis, Ph.D.  
Director  
Office of Premarket Approval  
Center for Food Safety  
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-226 HFS-235 HFS-246 HFS-247 HFS-13  
HFS-206 HFS-144 HFV-151 HFV-200 HFV-220 HFV-228 BNF0052